4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA-2011-N-0920]

RIN 0910-AG36

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting a final rule that published in the Federal Register of September 17, 2015. That final rule amended our regulation for current good manufacturing practice in manufacturing, packing, or holding human food to modernize it, and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. That final rule also revised certain definitions in our current regulation for registration of food facilities to clarify the scope of the exemption from registration requirements provided by the FD&C Act for "farms." The final rule published with some editorial and inadvertent errors. This document corrects those errors.

DATES: Effective: January 26, 2016.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2166.

SUPPLEMENTARY INFORMATION: In the Federal Register of Thursday, September 17, 2015 (80 FR 55908), FDA published the final rule "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" with some editorial and inadvertent errors. This action is being taken to correct inadvertent errors in the preamble and codified.

In FR Doc. 2015-21920, appearing on page 55908 in the Federal Register of Thursday, September 17, 2015, the following corrections are made:

1. On page 55908, in the first column, the headings section of the document, under the line containing "[Docket No. FDA-2011-N-0920]," is corrected by adding "RIN 0910-AG36".

2. On page 55938, in the second column, in the first paragraph under "VII. Comments on Proposed General Revisions to Current Part 110 (Final Part 117)," "revising provisions directed to preventing contamination of food and food-contact substances" is corrected to read "revising provisions directed to preventing contamination of food and food-contact surfaces."

3. On page 56151, beginning in the second column, revise § 117.8 to read as follows:

" **§ 117.8 Applicability of subpart B of this part to the off-farm packing and holding of raw agricultural commodities,**

Except as provided by § 117.5(k)(1), subpart B of this part applies to the off-farm packaging, packing, and holding of raw agricultural commodities. Compliance with this requirement for raw agricultural commodities that are produce as defined in part 112 of this

chapter may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter."

§ 117.405 [Corrected]

4. On page 56164, in the first column, in § 117.405 Requirements to establish and implement a supply chain program, paragraph (c) introductory text is corrected to read as follows:

"(c) When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when a non-supplier applies controls to certain produce (i.e., produce covered by part 112 of this chapter), because growing, harvesting, and packing activities are under different management), the receiving facility must:"

Dated: January 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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